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EXAMINER	
EASTWOOD, DAVID C	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,523	UEHATA ET AL.	
	Examiner	Art Unit	
	David Eastwood	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed 6/18/2010. Claims 1-21 are pending and an action on the merits is as follows.

Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-13 and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuhr et al. (US 2002/0040230)(here after referred to as Kuhr).

Regarding claim 1, Kuhr discloses a lancing apparatus (1) comprising a lancet holder (12) for retaining a lancet (3), the lancet including a main body (4) and a needle (6) projecting from the body, the lancet holder being moved in a lancing direction (7) from a standby position to a lancing position together with the lancet so as to cause the lancet to stick into an object (paragraph 30), the lancet being inserted into the lancet holder in a retreating direction opposite to the lancing direction (paragraph 41), thus to be retained by the lancet holder (paragraphs 30 and 41), wherein the lancet holder includes a first member (12a) and a second member (30) that are movable relative to each other (note progression of fig. 2-3), the second member being in direct contact

with the first member (note figure 4) and being movable relative to the first member between a fixing position (as depicted in fig. 2) in which the main body of the lancet is fixed to the lancet holder with a first fixing force (compressive force supplied by first member as depicted in fig. 2 and described in paragraph 30) for limiting axial removal of the lancet from the lancet holder and a non-fixing position (depicted in figure 3) in which the main body of the lancet is held by the lancet holder with a second fixing force (frictional force provided by the sleeve 38 in which lancet main body is set note fig 2 and 3 and paragraph 39) smaller than the first fixing force for facilitating axial removal of the lancet from the lancet holder.

Regarding claim 2, Kuhr discloses at least either of the first and the second members applies a pressing force to the lancet for fixing the lancet (note contact between lancet main body 4 and first member as depicted in fig. 2 further note paragraph 30).

Regarding claim 3, Kuhr discloses when loading the lancet, the lancet moves relative to the first member (note in figure 2 and 3 and note element 12a relative to lancet main body 4 in order to insert the lancet within the grasp of element 12a it would inherently have to move relative to it note reverse progression of fig. 3 to fig. 2 and further note paragraph 41), while the second member moves together with the lancet relative to the first member in the retreating direction from the non-fixing position toward the fixing position (paragraph 41), and wherein the lancet holder applies a greater pressing force to the lancet when the second member is located at the fixing position than when the second member is at the non-fixing position (note fixing force applied to

element 3 by element 12a as depicted in figure 2 when the second element 30 is in the retracted state as depicted in figure 2).

Regarding claim 4, Kuhr discloses fixing means (element 30 which abuts the proximal end of element 4 and element 12a which surrounds element 4 and correspond with indentations 4a as depicted in fig. 2) that applies a pressing force to the lancet for fixing the lancet when the second member is at the fixing position (note fig. 2 and further note paragraph 30).

Regarding claim 5, Kuhr discloses the first and the second members respectively include a first engaging portion (portions of element 12a which correspond with element 4a of main body 4) and a second engaging portion (distal end of element 30 which abuts the proximal end of element 4 note fig. 2) that are engaged with each other when the second member is at the fixing position (note contact between elements 30 and 12,12a as depicted in figure 4), the fixing means comprising the first and second engaging portions (note fig. 2).

Regarding claim 6, Kuhr discloses at least one of the first and the second engaging portions projects toward the other of the first and the second engaging portions (note the distal end of element 30 projects toward the distal end of element 12a as depicted in fig. 2).

Regarding claim 7, Kuhr discloses, one of the first and the second engaging portions comprises a recess (portion of element 12a formed by the radially inward projecting distal ends creating a recess between the leg portion and radially inward projecting portion of element 12a as depicted in fig. 3), and the other of the first and the

second engaging portions comprises a projection (distal end of element 30) to be fitted into the recess (note position of the distal end of element 30 relative to the aforementioned recess depicted in figure 3).

Regarding claim 8, Kuhr discloses the first member includes a pressing portion (projections of element 12a) that applies a pressing force to the lancet (note paragraph 30) and wherein the second member includes a working portion (distal surface of element 30) that displaces at least a part of the pressing portion from the lancet when the second member is located at the non-fixing position or between the non-fixing position and the fixing position (note progression of figures 2-3).

Regarding claim 9, Kuhr discloses the pressing portion includes a pair of movable portions (note the pressing portions are attached to the tongs 12a which move/deflect in order to release the lancet), wherein a gap is provided between the pair of movable portions for allowing the working portion to move (note the progression figures 2-3 where the working portion projects distally between the movable portions of element 12a), and wherein the gap is expanded when the working portion moves through the gap, so that at least a part of the movable portions is displaced so as to separate from the lancet (note when element 12a deflects to release the lancet the distance between the tongues' of 12a must increase in order to release the lancet which is driven by the distal end of element 30).

Regarding claim 10, Kuhr discloses at least one of the movable portions includes at least one cutaway (portioned defined by the radially inward projecting projection of element 12a and the elongate portion of 12a which encompasses element 30 as

depicted in fig. 3) that defines a part of the gap (note the cutaway as previously described defines a portion of the gap see also fig. 3), and that the working portion fits into (note aforementioned explanation and fig. 3).

Regarding claim 11, Kuhr discloses said at least one cutaway comprises a first cutaway portion into which the working portion is fitted in fixing the lancet (note position of element 30 relative to the cutaway as defined above as depicted in fig. 2), and a second cutaway portion into which the working portion is fitted in discharging the lancet (note position of element 30 relative to the cutaway as defined above as depicted in fig. 3).

Regarding claim 12, Kuhr discloses said at least one cutaway comprises a cutaway portion arranged to make the gap continuously or incrementally narrower when the working portion relatively moves with respect to the first member in the lancing direction (note in fig. 3 the cutaway as defined above comprises the radially inward projection portions of element 12a which taper in the lancing direction thus narrowing the gap between elements 12a).

Regarding claim 13, Kuhr discloses wherein the cutaway portion includes a tapered portion (note tapered portion distal the radially inward most point of the radially inward projecting portions of element 12a) that makes the gap wider continuously as proceeding in the lancing direction (note figure 3).

Regarding claim 16, Kuhr discloses wherein the pressing portion includes a fixed portion (protruded portion of element 12a fixed to element 12a) and a movable portion (portions of 12a which deflect in order to release the lancet as depicted in the

progression of figures 2-3), wherein a gap (space between the diametrically opposing portions of element 12a) is provided between the fixed portion and the movable portion for allowing the working portion to move (note figure 3), and wherein the gap is expanded when the working portion moves through the gap, so that at least a part of the movable portions is displaced so as to separate from the lancet (note progression of figures 2-3 where the moveable portions of 12a allow deflection of 12a releasing the lancet when the distal end of element 30 is moved in a distal direction note also paragraph 30 and 34).

Regarding claim 1 and 17, Kuhr discloses Regarding claim 1, Kuhr discloses a lancing apparatus (1) comprising a lancet holder (12) for retaining a lancet (3), the lancet including a main body (4) and a needle (6) projecting from the body, the lancet holder being moved in a lancing direction (7) from a standby position to a lancing position together with the lancet so as to cause the lancet to stick into an object (paragraph 30), the lancet being inserted into the lancet holder in a retreating direction opposite to the lancing direction (paragraph 41), thus to be retained by the lancet holder (paragraphs 30 and 41), wherein the lancet holder includes a first member (30) and a second member (12a) that are movable relative to each other (note progression of fig. 2-3), the second member being in direct contact with the first member (note figure 4) and being movable relative to the first member between a fixing position (as depicted in fig. 2) in which the main body of the lancet is fixed to the lancet holder with a first fixing force (compressive force supplied by second member as depicted in fig. 2 and described in paragraph 30) for limiting axial removal of the lancet from the lancet holder

and a non-fixing position (depicted in figure 3) in which the main body of the lancet is held by the lancet holder with a second fixing force (frictional force provided by the sleeve 38 in which lancet main body is set note fig 2 and 3 and paragraph 39) smaller than the first fixing force for facilitating axial removal of the lancet from the lancet holder, wherein the second member (as disclosed above) includes a pair of movable portions (deflection portions of 12a) for holding the lancet there between (note figure 2), and wherein the movable portions are displaced away from the lancet when the second member is relatively moved with respect to the first member in the lancing direction (when the aforementioned first member moves in a distal direction elements 12a must deflect/move in order to release lancet 3 from there grasp note progression of figures 2-3), but displaced toward the lancet when the second member is relatively moved with respect to the first member in the retreating direction (note in paragraph 30 and 41 when the aforementioned first member is retracted by insertion of the lancet the second member moves relative to the first member toward the lancet in order to engage the recesses 4a within lancet 3 note figure 2).

Regarding claim 18, Kuhr discloses wherein the lancet comprises a recess (4a), and wherein the movable portion comprises an engaging portion (radially inwardly portions of element 4a) to be engaged with the recess (note figure 2).

Regarding claims 1 and 19-20, Kuhr discloses a lancing apparatus (1) comprising a lancet holder (12) for retaining a lancet (3), the lancet including a main body (4) and a needle (6) projecting from the body, the lancet holder being moved in a lancing direction (7) from a standby position to a lancing position together with the

lancet so as to cause the lancet to stick into an object (paragraph 30), the lancet being inserted into the lancet holder in a retreating direction opposite to the lancing direction (paragraph 41), thus to be retained by the lancet holder (paragraphs 30 and 41), wherein the lancet holder includes a first member (12a) and a second member (proximal end of element 4) that are movable relative to each other (note progression of fig. 2-3), the second member being in direct contact with the first member (note figure 2) and being movable relative to the first member between a fixing position (as depicted in fig. 2) in which the main body of the lancet is fixed to the lancet holder with a first fixing force (compressive force supplied by first member as depicted in fig. 2 and described in paragraph 30) for limiting axial removal of the lancet from the lancet holder and a non-fixing position (depicted in figure 3) in which the main body of the lancet is held by the lancet holder with a second fixing force (frictional force provided by the sleeve 38 in which lancet main body is set note fig 2 and 3 and paragraph 39) smaller than the first fixing force for facilitating axial removal of the lancet from the lancet holder (note paragraph 39) and a pushing member (32) that moves the second member in the lancing direction (paragraph 43), wherein the pushing member (30) includes a working portion (distal ends of 31) that interferes with the second member (note in fig. 2 and 4-5 where the working portion abuts and thus interferes with the second member) and an operating portion (30) to be manipulated so as to move the working portion (paragraph 43).

Regarding claim 21, Kuhr discloses a lancing apparatus comprising a lancet holder (12) for retaining a lancet (3), the lancet including a main body (4) and a needle

(6) projecting from the body, the lancet holder being moved in a lancing direction (7) from a standby position to a lancing position together with the lancet so as to cause the lancet to stick into an object (paragraph 30), the lancet being inserted into the lancet holder in a retreating direction opposite to the lancing direction, thus to be retained by the lancet holder (paragraph 41), wherein the lancet holder includes a first member (30) and a second member (12a) that are movable relative to each other in a needle extending direction (note progression of fig. 2-3), the second member being in direct contact with the first member (note figure 4) and being movable relative to the first member between a fixing position (as depicted in fig. 2) in which the main body of the lancet is fixed to the lancet holder and a non-fixing position (as depicted in figure 3) in which the main body of the lancet is allowed to be removed from the lancet holder, the second member including a movable fixing portion (protrusions at the distal end of element 12a that correspond with recess 4a in the lancet body) that moves in a direction crossing the needle extending direction (radially outward note progression of fig. 2-3 and paragraph 30) for fixing contact with the main body of the lancet in response to the movement of the second member from the non-fixing position to the fixing position (as depicted in the progression of figures 2-3 and 7-9).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhr et al. (US 2002/0040230)(here after referred to as Kuhr) as applied to claims 1-13 above.

Regarding claims 14 and 15, Kuhr discloses wherein the cutaway portion includes a tapered portion that makes the gap wider continuously as proceeding in the lancing direction (note tapered portion depicted in figure 3 distal the radially inward most point of the radially inward projecting portions of element 12a) but fails to explicitly disclose wherein the cutaway portion includes at least one stepped portion that makes the gap wider sequentially as proceeding in the lancing direction. However, it would have been obvious to one skilled in the art at the time the invention was made to construct the tapered portion as disclosed by Kuhr with a series of stepped portions, since applicant has not disclosed that such a change in shape or form solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a tapered portion

of a cutaway portion that makes the gap wider sequentially as proceeding in the lancing direction. In re Dailey and Eilers, 149 USPQ 47 (1966).

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Eastwood whose telephone number is (571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. E./
Examiner, Art Unit 3731
8/5/2010

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 3731
August 13, 2010